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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,773

01/26/2004

Hrair Kirakossian

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03/29/2005

ACLARA BIOSCIENCES, INC.
1288 PEAR AVENUE
MOUNTAIN VIEW, CA 94043

EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/765,773	Applicant(s) KIRAKOSSIAN ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-8 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/04, 8/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear of what the role of the "capture antigen" is in the assay. What is its role in correspondence to the immunomagnetic isolation of rare cell type in the sample? What does it capture? Where is it located with regards to the rare cell, i.e. on the cell? See also claim 4 for the same problem.

Claim 4, line 15, is indefinite for reciting "combining...binding compounds, and second binding compounds.." . How many binding compounds are there? Do the "binding compounds" include "second binding compounds" ? Please clarify. Line 17 is confusing for reciting "such that". What does this "such that" lead to? Line 18 is also indefinite for reciting " forming such a complex". Which complex is it and what does it comprise of ? The last step "identifyingto determine the one or more biomarkers.." is inconsistent with the preamble of the claim "detecting one ore more protein-protein complexes..".

Claims 3, 6, 7, 8 recites abbreviations, e.g. ErbB, PI3K, Her1//Shc etc. Please spell out the abbreviations for abbreviations may contain more than one meaning.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 of U.S. Patent No. 6,627,400 B1 in view of Terstappen et al. (US 6,365,362).

Patent '400 recites a method for determining populations of each of a plurality of surface membrane proteins in a cellular sample, the method comprises the steps of: providing a binding compound for each of the plurality of surface membrane proteins, each binding compound having one or more eTag reporters attached thereto by a cleavable linkage, the one or more eTag reporters of each different binding compound having a different electrophoretic mobility so that eTag reporters of each different binding compound form distinct peaks upon electrophoretic separation; combining with the cellular sample a binding compound for each of the plurality of surface membrane proteins such that in the presence of a surface membrane protein a complex is formed between each surface membrane protein and the binding compound specific therefor; cleaving the cleavable linkage of each binding compound forming such complex so that

eTag reporters are released; and electrophoretically separating and identifying the released eTag reporters to determine the populations of the plurality of surface membrane proteins. The binding compound and the second binding compound are antibodies.

Patent '400 differs from the present invention by failing to claim that the above method can be used to detect one or more biomarkers of a rare cell type in a sample containing a mixed population of cells and a step of isolating the rare cell type by immunomagnetic separation.

Terstappen teaches a method for screening rare cells in a biological sample by contacting a biological sample containing a mixed cell population suspected of containing the rare cell of interest with magnetic particles coupled to a biospecific ligand (antibody) reactive with a rare cell determinant (capture antigen) or a class of determinants different than those found on blood cells; subjecting the resulted immunomagnetic sample to a magnetic field which is effective to separate the sample into an unlabeled fraction and a labeled, magnetic fraction including rare cell determinant. A second set of monoclonal antibodies, labeled with reporter molecules, are added to the sample and the cells are again magnetically separated in order to remove unbound reagent. Identifying the reporter. (see col. 7, line 45-col. 8, line 53).

It would have been obvious to one of ordinary skills in the art to isolate the mixed population of cells as taught by Terstappen before detecting biomarkers of rare cell type using the method of patent '400 since biomarkers or determinants on cell surface is

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considered cell surface protein and such isolation of subpopulation of cells would reduce non-specific binding and increase sensitivity in the detection of rare cell type.

Remarks

Claims 2-8 are free of prior arts.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
March 13, 2005


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
3/12/05